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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/079,640	05/15/1998	HENRY DANIELL	922.6588P	8567

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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

24

DATE MAILED: 11/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/072,640

Applicant(s)

Daniell

Examiner

FOX

Group Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

9/26/01

- ☒ Responsive to communication(s) filed on _____
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 3 - 213 is/are pending in the application.
- Of the above claim(s) 1, 85, 97-106, 108-117, 120-121, 123-167, 170, 177-180, 200-213 is/are withdrawn from consideration.
- ☒ Claim(s) 86-96, 173, 176 and 194-195 is/are allowed.
- ☒ Claim(s) 3, 171, 190-193, 196-199 is/are rejected.
- ☒ Claim(s) 4-84, 107, 118-119, 122, 168, 169, 172, 174, 175, 189 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 22
- ☒ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Art Unit: 1638

The request filed on 26 September 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/079,640 is acceptable and a CPA has been established. An action on the CPA follows.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The application should be reviewed for errors. Errors appear, for example, in claim 193, line 8, where --gene-- should be inserted after "tRNA(Ala)". It appears that this word was inadvertently omitted from this claim in the amendment of 26 September 2001. Errors also appear in newly amended claim 196, line 14, where the comma after "genome" should be deleted.

Applicant's amendment of 26 September 2001 has obviated the previously recited errors in the claims; the obviousness-type double patenting rejections of claims 2 and 196-199; the outstanding rejections under 35 USC 112, second paragraph; and the outstanding art rejections for claims 2-3, 171 and 198-199.

Newly submitted claims 202-213 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The claims are drawn to a chloroplast transformation vector comprising a gene of interest which encodes a non-proteinaceous product such as antisense RNA, a process for using that vector to transform crop plants, and the resultant crop plants. The subject matter of these claims corresponds to non-elected Group I as set forth in the Restriction Requirement of 10 September

Art Unit: 1638

1999. In the Election of 27 January 2000, Applicant elected Group II, drawn to chloroplast vectors comprising a gene encoding a proteinaceous product, and methods for their use.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 202-213 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 3, 171 and 190-192 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-23, 25-29, 31 and 34 of U.S. Patent No. 5,932,479. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons presented in the last office action for claims 2-3, 171, 190-192 and 196-199.

Claims 3, 171 and 190-192 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 119-120, 124, 132, 140-142, 153-157, 166-167 and 188 of copending Application No. 08/972,901. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons presented in the last office action for claims 2-3, 171, 190-192 and 196-199.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's intent to file Terminal Disclaimers is noted. The rejections will be maintained until the receipt of properly executed Terminal Disclaimers.

Art Unit: 1638

Claims 190-193 and 196-199 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 190-193, line 5, and claims 196-199, line 7, are indefinite in their recitation of "the coding sequences" which lacks antecedent basis in the claims. Replacement of "coding sequences" with --coding sequence-- would obviate this rejection.

Claim 192 is indefinite for failing to recite the target of the recombination in the last line, and for the omission of a period at the end. The claim appears to be incomplete. Insertion of the phrase -- with the homologous sequences in the target chloroplast genome. -- after the recitation of "sequences" in the last line would obviate this rejection.

Claims 3, 171, 190-192 and 196-199 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the intergenic spacer 2 region between the trnA and trnI genes of the chloroplast genome of higher plants, does not reasonably provide enablement for claims broadly drawn to the use of any intergenic spacer region which is highly conserved throughout higher plants and which may be used to facilitate homologous recombination and chloroplast transformation in a multitude of unrelated plant species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last office action for claims 2-3, 171, 190-192 and 196-199.

Art Unit: 1638

Claims 190-191 and 196-197 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the intergenic spacer 2 region between the trnA and trnI genes of the chloroplast genome of higher plants for the homologous recombination mediated integration of heterologous DNA into the intergenic spacer 2 region of the chloroplast genome of higher plants, does not reasonably provide enablement for claims broadly drawn to any intergenic spacer region for the integration of heterologous DNA into transcriptionally active regions of the chloroplast genome. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last office action.

Claim 192 remains rejected under 35 U.S.C. 102(b) as being anticipated by Zoubenko et al, as stated in the last office action for claims 2-3, 171, 192 and 198-199.

Claim 192 remains rejected under 35 U.S.C. 102(b) as being anticipated by Staub et al (1993), as stated in the last office action for claims 2-3, 171, 192 and 198-199.

Claims 3, 171 and 190-192 are rejected under 35 U.S.C. 102(b) as being anticipated by Staub et al (1995) in light of Sidorov et al (1999).

The claims are broadly drawn to a chloroplast transformation vector comprising a gene encoding a peptide of interest, said gene flanked by 5' and 3' regulatory sequences and chloroplast DNA flanking sequences, wherein said chloroplast DNA flanking sequences enable homologous recombination with transcriptionally active regions of the chloroplast genome. Claims 191 and

Art Unit: 1638

192 further recite the insertion into a “spacer” region of the chloroplast genome. The term “spacer” is broadly interpreted to mean any chloroplast DNA sequence, in contrast to the term “intergenic spacer” which implies the sequences between two genes. The insertion into transcriptionally active regions has an effective filing date of 7 August 1997, the filing date of the earliest provisional application, since this subject matter was not disclosed in the earlier filed parent applications.

Staub et al (1995) teach a chloroplast transformation vector comprising a *uidA* gene encoding a beta-galactosidase protein, flanked by a 5' ribosome binding site and a 3' polyadenylation region, both flanked by regions of homology from the tobacco chloroplast genome comprising the *rbcL* and *accD* genes, wherein the vector was inserted into a transcriptionally active “spacer” region of the tobacco chloroplast genome, namely the *rbcL* structural gene, as evidenced by transcription of the *uidA* gene by the native *rbcL* promoter (see, e.g., page 845, column 2, bottom paragraph; page 846, Figure 1 and second full paragraph of column 2; page 847, column 2, first full paragraph). The vector would also inherently be able to be inserted into the chloroplast genome of a plant other than tobacco, as evidenced by Sidorov et al (1999) who teach that tobacco chloroplast regions of homology comprising the *rbcL* and *accD* genes were sufficient to enable homologous recombination into the potato chloroplast genome (see, e.g., page 209, Abstract; page 210, Figure 1).

Claims 4-84, 86-96, 107, 118-119, 122, 168-169, 172-176, 189 and 193-199 are deemed free of the prior art, as stated in the last office action for claims 4-84, 86-96, 107, 118-119, 122,

Art Unit: 1638

168-169, 172-176, 189-191 and 193-197. The prior art also fails to teach or suggest a method of chloroplast transformation comprising the use of a vector comprising chloroplast DNA flanking regions from a plant species other than the target plant species.

Claims 4-84, 107, 118-119, 122, 168, 169, ~~172~~¹⁷², 174-175 and 189 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 86-96, 173, 176 and 194-195 are allowed.

Applicant's arguments filed 26 September 2001, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicant urges that the first enablement rejection is improper, given the disclosure in the specification of methods to identify other appropriate spacer regions, and the ability of other workers to obtain said regions and successfully transform chloroplasts. The Examiner maintains that the mere suggestion of techniques for spacer isolation does not preclude the need for an undue amount of trial-and-error experimentation, in view of the unpredictability previously set forth by the Examiner.

Regarding the newly cited references, it is unclear whether these references utilized the techniques of the instant specification to identify and isolate their spacer regions. In the absence of a declaration under 37 CFR 1.132, it appears that other techniques were utilized by these workers in these later-published references. See In re Glass, 181 USPQ 31, 34 (CCPA 1974), which teaches that references published after the filing date of an application may not be relied

Art Unit: 1638

upon for the enablement of the specification. Furthermore, with the exception of Sidorov et al, it appears that the other workers transformed the same plant species as the source of the chloroplast flanking DNA sequences in the vector, and none of the references teach the insertion of heterologous DNA into transcriptionally silent *intergenic spacer* chloroplast genomic regions, in contrast to the instant claims.

Applicant urges that the second enablement rejection is improper, given the ability of an intergenic region to be transcriptionally active as taught by Staub et al (1995). The Examiner maintains that Staub et al actually inserted into an existing *rbcL* gene, rather than an intergenic region, as stated above.

Applicant urges that the art rejection over Zoubenko et al is improper, given the failure of the reference to teach conserved intergenic spacer regions. The Examiner maintains that claim 192 is not drawn to a vector comprising an intergenic spacer region. Furthermore, Applicant's assertions on pages 14-15 of the amendment of 26 September 2001, that a variety of conserved intergenic spacer regions exist, negates the general discussion in the specification that these regions are not generally conserved. As the claim is not drawn to a particular intergenic spacer region, it is reasonable to assume that it would encompass a conserved region which would not be different from that taught by Zoubenko et al.

Applicant urges that the art rejection over Staub et al (1993) is improper, given the failure of the reference to teach the use of the vector to transform a plant species different than the plant species from which the chloroplast DNA flanking sequences were derived. The Examiner

Art Unit: 1638

maintains that the recitation of a "target plant species" in a vector claim is equivalent to an intended use, which is given little patentable weight in a product claim. The vector taught by the reference comprises every element of the claimed vector, including chloroplast DNA flanking sequences. The claim is not directed to a process for transforming a target plant species with a vector comprising flanking chloroplast DNA sequences from a different plant. Furthermore, the ability of the tobacco flanking sequences to work in a non-tobacco plant would have been an inherent property, as demonstrated by Sidorov et al (1999).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

November 15, 2001

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 163A

